


Center for Nanophase Materials Sciences Quality Assurance Plan

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1. Purpose

This plan identifies the quality assurance (QA) requirements for the Center for Nanophase Materials Science (CNMS) and describes the systems and methods utilized to ensure the requirements are met. The project will be conducted in accordance with the *Center for Nanophase Materials Science Project Execution Plan*, U.S. Department of Energy (DOE) Order O 414.1A, *Quality Assurance*, and Title 10 of the Code of Federal Regulations, 10 CFR 830, Subpart A. This plan addresses the ten criteria of DOE O 414.1A.

2. Scope

This plan provides requirements applicable to all project activities performed by or for the CNMS Project, from construction through commissioning. The CNMS facility will be built on the ORNL Spallation Neutron Source (SNS) Site and will use the same architect-engineer/construction manager (AE/CM). This QA plan is formulated to implement the applicable portions of the quality program established for the SNS. It also implements the applicable quality system components described in the ORNL Quality Assurance Program Description. The QA plans developed by the AE/CM for the SNS will govern work in their areas of responsibility for the CNMS.

3. Definitions

As used in this plan:

Acceptance Criteria Listing (ACL)—a document listing the criteria that will be checked to make an item or service acceptable.

Quality—"Fitness of an item or design for its intended use."

Quality Assurance (QA)—The set of actions taken to avoid known hazards to quality and to detect and correct poor results.

Quality-assuring actions—Planning, analyses, documentation, and other actions necessary to comply with requirements and ensure that goals are achieved.

Safety—Environment, safety, and health (ES&H), including pollution prevention and waste minimization, as in the DOE Integrated Safety Management Systems (ISMS) definition.

4. Graded Approach

This is a comprehensive plan that covers a variety of systems, components, and activities. Quality-assuring actions shall be applied commensurate with needs. Three grade levels (quality levels) are defined:

1. **Serious** potential impacts, requiring a **disciplined** set of actions.
2. **Moderate** potential impacts, justifying a **balanced** set of actions.
3. **Routine** potential impacts, justifying a **flexible** approach.

Tables 1 and 2 explain the process.

PLEASE NOTE: Consultation with a quality assurance representative is expected whenever grade levels are being determined, because there are many factors to consider. This discussion is only an overview of the process.

First determine the grade level in Table 1, and then apply appropriate actions from Table 2.

Table 1. Determination of quality level

| Risk Type Level | 1. Serious Level | 2. Moderate Level | 3. Routine |
|---------------------------------|---|---|---|
| Functional | Potential for a significant adverse impact to completion of the CNMS project or to achieving key performance goals | Potential for a moderately adverse impact to the CNMS facility or equipment. | Potential for negligible impact to the CNMS facility or equipment. |
| Environment, safety, and health | Potential for (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, or (2) environmental damage that could exceed regulatory limits or involve significant cleanup costs. | Potential for injury or illness requiring hospitalization, temporary or partial disability, or moderately adverse impact on the health or safety of a worker or the public. | Potential for (1) minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization, or (2) a negligible impact on the environment. |
| Cost | Potential for a financial loss of \$500K or more. | Potential for a financial loss of \$50K or more. | Potential for a financial loss less than \$50K. |
| Compliance | Potential for inadvertent noncompliance with state and federal laws and regulations or DOE requirements. | Potential for inadvertent noncompliance with administrative orders or procedures established by the CNMS or ORNL. | Potential for minor noncompliance with established management practices. |

Table 2. Actions appropriate to quality levels^a

| | Level 1. Disciplined | Level 2. Balanced | Level 3. Flexible |
|---------------|---|--|--|
| Action | Design reviews and <i>independent</i> verifications | Design reviews and verifications | Little or no design reviews, verification, or validation |
| | Thorough documentation | Adequate and appropriate documentation | Minimal documentation |
| | Established acceptance criteria listing (ACL) | Established ACL | ACL not required |
| | Vendor qualification and surveillance | Vendor qualification (questionnaire minimum) | Little or no vendor qualification |
| | Formal procedures | Procedures as needed | No formal procedures except ES&H (i.e., follow good practices) |
| | Complete oversight and assessment activities | Oversight covered under general management assessments | Oversight performed by line supervision |
| | Controlled measuring and test equipment (M&TE) | Controlled M&TE | M&TE generally not used |
| | Documented worker qualifications | Knowledgeable personnel employed | Knowledgeable personnel employed |
| | Formal inspection and testing | Tests and inspections conducted appropriately | Normal receipt inspection only (except where ES&H requires more) |
| | QA approvals are required | QA representative consultations are required | QA consultations are available |

^a To determine the grade and subsequent actions for an item or activity, first locate the appropriate risks on the matrix in Table 1. Example: Selection of any one of the four risk types in level 1 makes all the actions come from level 1.

5. DOE Quality Criteria Discussion

Criterion 1—QA Program

Organization and Functional Responsibilities

The CNMS project is an ORNL project co-located with the SNS on the SNS site. The contracted SNS AE/CM team will be responsible for the design and construction of the conventional facilities, as well as the quality assurance planning and implementation associated with these activities. A suite of technical equipment will be procured and installed in the facility. The focus and emphasis of this quality plan are the systems, activities, and methods used to ensure that all activities associated with procurement, installation, and use of this equipment is conducted in an optimized manner.

Responsibility for Managing

The Project Director is responsible for the project. The Project Director manages the project and is responsible for achieving performance goals. The CNMS QA manager (QAM) is responsible for ensuring that a quality system is established, implemented, and maintained in accordance with requirements.

Levels of Authority and Interface

The *Center for Nanophase Materials Science Project Execution Plan* and this QA plan define the responsibility, authority, and interrelation of personnel who manage, perform, and verify work that affects quality.

Roles and responsibilities addressed in this plan include the following.

Responsibility for performing work—All staff and subcontractors are responsible for the quality of the work that they do and for using guidance and assistance that is available. This responsibility includes the expectation of stopping work when questions emerge based upon environmental, safety, health, quality, or other potential project-impacting issues or concerns.

Responsibility for acceptance—The project managers responsible for the CNMS conventional facilities and the technical equipment are required to determine their acceptance criteria. For quality levels 1 and 2, documentation using ACLs as required.

Responsibility for assessing work—Management at each level is responsible for evaluation through self-assessments. Project management may request independent assessments.

QA Program—The CNMS QAM is responsible for development, implementation, assessment, and improvement of the QA program.

Periodic reporting—The QAM is responsible for periodically reporting on the performance of the quality system to the project director for her review and as a basis for improvement of the quality system.

Readiness assessments—The project director or higher authority may call for readiness

assessments as the project nears completion.

Planning and scheduling—Planning and scheduling of the project is organized around a work breakdown structure (WBS) and the associated WBS dictionary.

Resource considerations—Managers are responsible for providing the resources needed to conduct the project successfully. Spending is monitored and appropriate reports prepared to ensure that financial profiles meet project expectations and performance goals.

Criterion 2—Personnel Training and Qualification

The CNMS project managers are responsible for providing the resources to ensure that staffs are adequately trained and qualified to perform their assigned work. Note: ES&H training requirements for the CNMS construction project are provided in ORNL ISMS programs, including the *CNMS Environmental Safety and Health Plan*. Project managers and team members are responsible for ensuring that their training and qualification requirements are fulfilled, including continuing training to maintain proficiency and qualifications.

Criterion 3—Quality Improvement

Processes to detect and prevent quality problems will be established, including equipment inspections and verifications; design reviews; baseline change reviews; and work planning. Item characteristics, process implementation, and other quality-related information will be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Problems identified by assessment, analysis, test, inspection, and other means will be controlled and corrected using the graded approach described in this plan. Acceptance criteria listings (ACLs) and the ACL database will be the primary tools used to track conformity of CNMS items.

Occurrence reporting will be as required by DOE. Where appropriate, the cause(s) of the problem will be identified and corrected to prevent recurrence.

All project personnel and subcontractors are encouraged to identify problems and may do so without fear of reprisal or recrimination.

Items, services, and processes that do not conform to specified requirements shall be identified and controlled to prevent their unintended use. Inspection discrepancy reports, nonconformance reports or similar tools will be used to implement this requirement.

Criterion 4—Documents and Records

Documents shall be prepared, reviewed, approved, issued, used, and revised to describe processes, specify requirements, or establish design. CNMS project managers will use the graded approach described in this plan to determine work in their scope that requires the preparation of controlled documents.

Required records shall be specified, prepared, reviewed, authenticated, and maintained.

Guidelines will be established to aid in the selection of information and processes for storing and maintaining records for the project in accordance with DOE and National Archives and Records Administration records requirements. Project management and team members are responsible for identifying the information to be preserved in accordance with the CNMS Records Inventory and Disposition Schedule (RIDS).

Criterion 5—Work Processes

Resources—CNMS project managers will provide the resources and support systems needed to enable their staffs to do their work using methods that promote successful completion of tasks, conformance to CNMS requirements, and compliance with ES&H rules.

Graded Approach—CNMS management will use the graded approach described in this plan to determine the appropriate work controls based on the type of work being done. CNMS QA representatives may assist in these determinations.

Safety—CNMS management will ensure that management of ES&H functions and activities are an integral and visible part of the work planning and execution processes, including use of ISMS guiding principles and worker participation in work planning.

Training—CNMS management will ensure that employees and subcontractors are properly trained in and are knowledgeable of the procedures, instructions, drawings, specifications, and other related administrative and technical documents that control their work. Where processes require specially qualified personnel, the performing personnel shall be appropriately trained and certified to the qualified process/procedure before performing those processes.

Work Planning—Work on the CNMS Project shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.

Acceptance Planning—Systems or components that are determined to be quality level 1 or 2 should have plans for acceptance based on the creation and completion of ACLs.

Conduct of Work—Work shall be performed safely, in a manner that ensures adequate protection for employees, the public, and the environment, and management shall be accountable for the safe performance of work. Employees and management shall exercise a degree of care commensurate with the work and the associated hazards. See the *ES&H Plan* for more details on CNMS safety management systems.

Item Control and Protection—Items, including consumables, shall be identified and controlled to ensure their proper use and prevent the use of incorrect, unaccepted, or unidentified items. The project will define a system of controls to ensure that items are handled, stored, shipped, cleaned, and preserved to prevent them from deteriorating, being damaged, or becoming lost. These controls will be established according to instructions, specifications, drawings, and technical manuals for items that are sensitive, have a high cost, or have been identified as having a significant impact on the environment or schedule.

Calibration—Equipment used for process monitoring or data collection shall be calibrated and maintained. Calibration will be controlled by a system or systems making appropriate use of qualified calibration service providers, equipment calibration-status tracking database(s), and approved methods for adding equipment items to the controlled system. The QAM will oversee

and support the calibration system.

Criterion 6—Design of Conventional Facility

Principles and Standards—Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Applicable requirements and design bases shall be used in the design.

Graded Approach—The CNMS Project will use the system of formal controls for creating, documenting, and verifying designs established for the SNS Project. The formality of design control activities will be determined based on the scale, cost, complexity, and hazards associated with the item, using the graded approach described in this plan.

Changes—Design changes, including project change orders, field changes, and nonconforming items designated "use-as-is" or "repair," shall be controlled by measures commensurate with those applied to the original design. Temporary modifications will have a level of control similar to the design of permanent modifications if they affect a quality level 1 or 2 system.

Configuration management—Systems will be implemented to control designs and to inform facility operators of the current configuration of equipment in the facility. Configuration management and control is discussed in the SNS *Project Controls Manual* and configuration management procedures.

Verification and Validation—Verification and validation of design are established through many layers of review from inception to startup, such as the following:

- Requirements are reviewed during the project-planning phase.
- Design documents are reviewed during creation by design organization internal reviews.
- Designs are further reviewed by formal multidisciplinary design review teams where warranted.
- Acceptance tests will prove the adequacy of equipment and systems.
- A readiness assessment is conducted before startup.

Definitions

Design—Description that can be used to create a final end-use product, such as assembled structures, etc. (also called design-output or design product).

Design inputs—Customer requirements and preferences for the features and performance of the end product and the customer's additional constraints on the design process, such as due dates, design deliverables, and codes and standards.

Design interfaces—Parts, systems, or module interfaces as well as organizational interfaces involved in coordinating the design process.

Design controls—Design control measures (such as procedures and training) provided to ensure the following:

- Selected design methods are suitable for the intended application.
- Design personnel have access to information applicable to establishing the design basis.
- Interfaces between the scopes of design are defined and coordinated to ensure compatibility.
- Design output contains sufficient detail to permit verification that it meets the design-input requirements.
- The design is documented adequately to support analysis, construction, operation, and maintenance. The design basis, as well as the detailed design outputs developed from it, will be included in the records.

Design Verification and Validation

Independence—Different degrees of independent verification are required for designs depending on their graded-approach categories. The adequacy of design inputs, processes, outputs, and changes shall be verified or validated by the following:

- Level 1. Verification and validation by individuals or groups independent from those who created the design and who will not benefit from, or have the appearance that they could benefit from, any lack of objectivity.
- Level 2. Verification and validation by individuals or groups other than those who created the design but who may be supervised or managed by the same person.
- Level 3. Some independent verification and validation as a recommended practice.

Verification and validation work will be completed before approval and implementation of the design.

The design will be verified to an extent commensurate with its importance to safety (see Table 1), complexity of design, degree of standardization, state of the art, and similarity to proven design approaches. Acceptable verification methods include but are not limited to any one or combination of (1) design reviews, (2) alternate calculations, and (3) prototype or qualification testing and comparison of the new design with a similar proven design, if available.

Where the design method involves the use of computer software to make design calculations or dynamic models of the structure, system, or component's functionality, that software must have been demonstrated to produce validated results. The demonstration needs to be documented in a formal report of validation that is maintained in records that are accessible for inspection. However, exemptions may be made for commercially available software that is widely used and for codes with an extensive history of refinement and use by multiple institutions, if the validation is evidently unlikely to reveal a problem and is difficult and/or expensive to complete. Exemptions affecting quality level 1 or 2 systems or components should be documented.

Design validation shall be performed to ensure that the design product conforms to defined project needs and/or requirements. Design validation follows successful design verification. Designs shall be validated, preferably before procurement, manufacture, or construction, but no later than acceptance and use of the item.

Validation Criteria—The design shall

- meet the design-input requirements,
- contain or make reference to acceptance criteria, and
- identify those design characteristics that are crucial to the safe and proper functioning of the equipment or system.

Each independent inspection, test, or review will feed the evaluation process, which is a comparison of results with acceptance criteria to determine acceptance or rejection, or the need for corrective action. In some cases the outcome may be to seek adjustments to requirements.

The formality of reporting will escalate as the significance of the review or test increases. Higher levels of management must be aware of and participate in the correction of the most significant problems.

Required design analyses and calculations will be performed and documented. The resulting documentation should include the assumptions, actual calculations, design inputs, references, and units in sufficient detail such that a technically qualified person could review and understand the analyses and verify the results.

Design-output documents will be reviewed and approved before release.

Criterion 7—Procurement

Procurement controls will be implemented to ensure that purchased items and services meet project needs and comply with applicable quality requirements. CNMS personnel requesting procurement of items and services are responsible for providing technical, quality, ES&H, and other specifications that adequately describe the item or service being procured so that the supplier can understand what is desired and what will be accepted. Development of these specifications may be achieved through the involvement of QA representatives and through established review and approval systems. The following factors should be considered:

- technical performance requirements,
- appropriate standards,
- laws and regulations, and
- acceptance criteria.

Suppliers of quality level 1 or 2 items or services should be evaluated to determine their ability to provide acceptable items and services. The evaluation typically includes reviews by the QA representative. QA representative approval is mandatory for level 1, and consultation is required for level 2 procurements, as noted in Table 2. QA representative consultation is available for level 3 procurements where needed.

Previously accepted suppliers should be appropriately monitored to ensure that they continue supplying acceptable items and services. Source surveillance is the recommended method to ensure that items are free of damage and that specified requirements were adequately met. Incoming items will be verified against previously established acceptance criteria. Unacceptable items or services should be documented. A record of supplier performance will be kept for future procurement consideration.

Counterfeit/Suspect Parts—Counterfeit/suspect parts are prohibited. Inspections will be used

to detect violations. When counterfeit/suspect parts are found, they will be identified, segregated, and disposed of in accordance with DOE G 440.1-6, *Implementation Guide For Use With Suspect/Counterfeit Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830, Subpart A, and DOE O 414.1A, Quality Assurance*.

Criterion 8—Inspection and Acceptance Testing

Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria.

Acceptance Criteria Listings—ACL forms and the ACL database are the primary tools used to organize this activity.

Graded Approach—Inspections will be conducted in accordance with the graded approach (Table 2).

Calibration—Equipment used for inspections and tests shall be calibrated and maintained. Calibration will be controlled by a system or systems making appropriate use of qualified calibration service providers, equipment calibration-status tracking database(s), and approved methods for adding equipment items to the controlled system. The QA representative will oversee and support the calibration system.

Criterion 9—Management Assessments

CNMS management shall regularly evaluate achievement relative to performance requirements and shall appropriately validate or update performance requirements and expectations to ensure quality. The management assessment process shall periodically include an evaluation of the organization's products and processes to determine whether the project's missions are being fulfilled. The results of management assessments, which focus on means to improving the quality of work performed, shall be reported to the appropriate responsible line or project management level.

When performance does not meet established standards, management shall, with the assistance of others with appropriate expertise, determine the cause and initiate corrective action. QA representatives may assist, lead, or facilitate cause investigations.

Criterion 10—Independent Assessments

Independent assessments of the CNMS Project can be sponsor driven or be requested by the CNMS project director. Independent assessments typically focus on quality or ES&H management systems, self-assessment programs, or other organizational functions identified by management. Project-based assessments including project reviews, readiness assessments, and other similar technical evaluations shall also be considered a component of the independent assessment process. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed. A qualified lead assessor (auditor) is required, and the team may include other subject-matter experts to evaluate the adequacy and effectiveness of activities if they are not responsible for the work being assessed. **AE/CM**—The AE/CM will receive independent assessments in accordance with the contract.

6. References for use with this plan

10 CFR

10 CFR 830, Subpart A, "Quality Assurance Requirements"

DOE

O 414.1A, *Quality Assurance*

G 414.1-2, *Quality Assurance Management System for use with 10 CFR Part 830.120 and DOE O414.1*

G 440.1-6, *Implementation Guide for use with Suspect/Counterfeit Items Requirements*

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